

510(k) Summary

SEP 29 2011

Trade Name: Scepter C Occlusion Balloon Catheter

Generic Name: Occlusion Balloon Catheter

Classification: Class II
MJN – Catheter, intravascular occluding, temporary
21 CFR 870.4450 – Vascular clamp

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.
714-247-8000

Date Prepared: March 15, 2011

Contact: Naomi Gong

Predicate Device:

Number	Description	Clearance Date
K091458	ev3 Neurovascular – HyperForm and HyperGlide Balloon System	October 15, 2009

Device Description:

The Scepter C Occlusion Balloon Catheter is a dual coaxial lumen catheter with a non-detachable low inflation pressure compliant balloon attached to the distal end of the catheter. The catheter is designed to track over a steerable guidewire. Radiopaque marker bands are located at ends of the balloon and distal tip of the catheter to facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories. The catheters are packaged sterile for single use only.

Indication For Use:

The Scepter C Occlusion Balloon Catheter is intended for use in the peripheral and neurovasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

Verification and Test Summary:

Pre-clinical Testing	Result
Surface and physical attributes	Pass
Tensile strength	Pass
Leakage (liquid and air)	Pass
Static and dynamic burst pressure	Pass
Simulated use	Pass
Compatibility with devices	Pass
Kink resistance	Pass
Catheter flexural fatigue	Pass
Hydrophilic coating	Pass
Hub testing	Pass
Torque testing	Pass
Balloon testing – burst, compliance, deflation time, fatigue	Pass
Animal testing – acute study compared to predicate device	Pass
Bicompatibility testing (ISO 10993-1)	Pass

Technological Comparison:

	Predicate Device (K091458)	510(k) Subject Device
Intended Use	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.	Same
Lumen configuration	Single lumen	Dual coaxial lumen
Inner Diameter	0.010"	0.0165"
Outer Diameter	2.2 – 2.8 F	2.6 – 2.8 F
Balloon Diameter/Length	3-5 mm/ 10-30 mm	4 mm/10-20 mm
Material	Polyether block amide, polyolefin, stainless steel, PTFE, chronoprene, Pt alloy, polypropylene	Polyether block amide, polyolefin, stainless steel, PTFE, polyurethane elastomeric alloy, Pt/Ir, nylon
No. of Markers	2	3
Coating	Hydrophilic coating	Same
Guidewire compatibility	0.010" wire	0.014" or smaller wire
Method of supply	Sterile and single use	Same

Summary of Other Information:

Other information provided in the 510(k) included published studies of balloon use. In addition, an in vivo animal study demonstrated safety including performance/handling.

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Scepter C Occlusion Balloon Catheter when compared with the predicate device, ev3 HyperForm and HyperGlide Balloon System (K091458).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are sterilized using same methods and processes.

In summary, the Scepter C Occlusion Balloon Catheter described in this submission is, in our opinion, substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MicroVention, Inc.
c/o Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

SEP 29 2011

Re: K110741

Trade/Device Name: Scepter C Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: July 29, 2011
Received: August 01, 2011

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

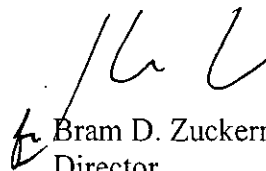
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K110741

Device Name: Scepter C Occlusion Balloon Catheter

Indications For Use:

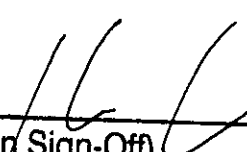
The Scepter C Occlusion Balloon Catheter is intended for use in the peripheral and neurovasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Cardiovascular Devices510(k) Number K110741